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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777.849

02/12/2004

Samuel Chackalamannil

CV01148KB

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7590

08/02/2006

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/777,849	Applicant(s) CHACKALAMANNIL ET AL.	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-12, 22, 23, 28-30, 34, 35, 37, 39, 41, 42 and 45-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-12, 22-23, 28-30, 41-42, 45-51 is/are rejected.
- 7) ☒ Claim(s) 34, 35, 37 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/22/2006 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"Thioalkyl", which occurs in the definition of the substituents on page 6 and elsewhere, is not standard nomenclature. Thio as a generic prefix simply indicating the presence of sulfur. It could have a number of possible meanings. It is possible that the term refers to HS-alkyl-, which is properly called the mercaptoalkyl group. It is also possible that it is intended to refer to the alkyl-S- group, which is properly called the alkylthio group. It could possibly refer to the replacement of a carbon in an alkyl with a Sulfur, e.g. CH₃-S-CH₂-. Another alternative is that the sulfur could be a double bonded substituent (rather than a single bonded one as seen in mercaptoalkyl), e.g. CH₃-C(=S)-CH₂-, properly

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called the thioxo alkyl. There might be some letters missing, so that what was intended was thiophenylalkyl, i.e. the alkyl is substituted by thiophene, or possibly thionoalkyl, i.e. alkyl substituted by =C=S . This specification gives no clear evidence as to which of these plausible choices was originally intended. The earlier traverse was unpersuasive. First, even if applicants' reasoning were correct, and one could infer that what was really intended was mercaptoalkyl, the wording is still incorrect. As stated in *In re Zletz*, 13 USPQ2d 1320, 1322, "An essential purpose of patent examination is to fashion claims that are precise, clear, correct and unambiguous." This term is not correct. Second, the inference drawn is not supported. It is of course true that when a substituent appears on a stem, the substituent always appears at the left, and the stem at the right. That is the only way that substituents are ever correctly done. The fact that the specification has for example "hydroxyalkyl" simply reflects that applicants are using standard nomenclature. However, one cannot assume such a situation here because "thio" is, unlike "carboxy", not the name of a substituent. And even if one could, applicants have presented no reason for assuming that "thio" means a singly bonded sulfur, i.e. HS- , rather than a doubly bonded sulfur, i.e. S= . The later traverse is also unpersuasive. Applicants argue that it is clear that this "refers to an alkyl group that is substituted with a thio group." The problem is that there is no such thing as a thio group. Thus, at the first point, one must decide whether this is an alkyl substituted by some sulfur group, or whether the error has simply been to write the substituent backwards, i.e. that the true group is alkylthio. There is no guidance in the specification directing one to reject the latter in favor of the former, as both are plausible. And even if one decided that it is the former, what is the substituent? Is the S single bonded (HS) or double bonded (S=)? Applicants have given no reason at all for selecting the

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former rather than the latter. The examiner must point out the name of the latter, "thioxo", is actually closer than the name for the former, "mercapto".

Claims 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim 51 formula is problematic. If the material in parenthesis is correct, then n and m can only be 2 (i.e. the material in parenthesis is $-\text{CH}=\text{CH}-$). Note that carbon must have 4 bonds. If e.g. $m=3$, then two carbons will be taken care of with $-\text{CH}=\text{CH}-$ but the third will have only three bonds. Moreover, this conflicts with the requirement that the ring must be saturated, as is stated on page 12, line 7 of the specification. The earlier traverse was unpersuasive. Applicants argued that R10 or R11 can provide the missing substituent. However, substituents by their definition, substitute, which means that they replace a H with themselves. Thus, they cannot provide something which is missing. Moreover, even if this were true, as noted, page 12, line 7 of the specification requires that the ring be saturated. The later traverse on the issue of the R11 and R10 substituents is also unpersuasive. The argument simply doesn't match the actual claim language. A substituent is by definition something which replaces a H atom, and thus it cannot solve any problem with missing valences. The claim has no requirement that it even be on the problematic carbons. It could replace a $\text{R}_9=\text{H}$ hydrogen, the $\text{R}_6=\text{H}$ hydrogen or the hydrogen of the "CH". Further, given that the ring is supposed to be saturated (see page 12, line 7), if either m or n were greater than 1, applicants will still be short, because there are only two substituents given. For example, if $m=n=2$, then there will be 4 moieties needed, but the structure provides for only two. Thus, the very fact that variable choices of greater than 1

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are given for m and n mitigates against this explanation, since it will not work in those cases. The remarks do not discuss how applicants' theory can rescue the $m > 1$ or $n > 1$ problem.

Claim 51 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The replacement of "ester" with $-\text{COOR}^{50}$ in R9 is new matter for the same reason that the thioalkyl replacement was deemed new matter previously. How does one know that the intended substituent looked like that? It could just as well have been the other way around e.g. $-\text{OCOR}^{50}$. Or it could have been $-\text{CH}_2\text{COOR}^{50}$, $-\text{OCOOR}^{50}$ or $-\text{OCONR}^{50}\text{R}^{51}$, which are additional ester type moieties, just to name one other choice. An error can be corrected provided that there is not "reasonable debate" as to what the correct text would be, *Novo Industries, L.P. vs. Micro Molds Corp.*, 350 F.3d 1348, 69 USPQ2d 1128 (2003). Here, clearly there is more than one possibility, as was the case in *Novo Industries* as well. In such a case, one must show that one of ordinary skill in the art would have been able to determine for sure what was intended, *Ex parte Brodbeck*, 199 USPQ 230. Similarly, MPEP 2163.07 states that correcting an error without introducing new matter requires "one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction." Such a burden has not been met, since there are many possibilities as to what could have been intended.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-12, 22-23, 28-30, 41-42, 45-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-11 of U.S. Patent No. 6821978. Although the conflicting claims are not identical, they are not patentably distinct from each other because of overlap.

The claims in this case are drawn to R4 as optionally substituted heterocycloalkyl, e.g. tetrahydropyranyl as see in e.g. claim 42. However, the parent case also has

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tetrahydropyranyl in its claims 10-11. It is not at all clear why that material is present in the patent.

Traverse is unpersuasive. The Obviousness-type Double Patenting rejection will be retained until the Certificate of Correction request is actually approved. Not all Certificate of Correction requests are approved, especially ones, such as this one, which go beyond clerical or typographic errors.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663.

The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


**Mark L. Berch
Primary Examiner
Art Unit 1624**

7/27/06